

Opticap® XL5 Capsule Filler
with Millipore Express® SHF Hydrophilic Membrane

0.2 µm Rated

Catalogue Number: KGEPA05T11
Lot Number: C9MN45634

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO® 9001 Quality Systems Standard.

Non-Fiber Releasing

This product was manufactured with a Millipore Express SHF membrane which meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

Component Materials Toxicity

Component materials were tested and meet the criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

100% Integrity Testing in Manufacturing

Each unit must pass the Millipore integrity test correlated to the *Brevibacterium diminuta* ASTM® FR38 bacterial challenge test.

Validated Production Process

This product was fabricated using a validated manufacturing process. Principles of statistical process control and determinations of process capability have been applied to critical variables in the cartridge fabrication process. In-process controls are used to assure stability of the process.

Indirect Food Additive

All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182.

Alcohol Reference Test

Sterilizing-grade (0.22 µm) hydrophilic Millipore Express SHF membrane is certified to a bubble point equal to or greater than 18.5 psig (1276 mbar) in a 70%/30% IPA/water mixture with nitrogen at 23° C.

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3(3) of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3(3) of this Pressure Equipment Directive, this product does not bear the CE mark.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

USP Bacterial Endotoxins

A sample aqueous extraction contains less than 0.25 EU/mL as determined using the Limulus Amoebocyte Lysate (LAL) test.

Integrity

Samples exhibited a water bubble point equal to or greater than 58.0 psig (4000 mbar) with air at 23° C.

Samples exhibited an air diffusional flow rate of less than or equal to 16.4 cc/min at 40 psig (2753 mbar) in water at 23° C.

Flow Rate and Pressure Drop

Samples met a maximum pressure drop of 3.2 psid (221 mbar) at 2.0 gpm (7.6 L/min) with clean water at 23° C.

USP Oxidizable Substances

Effluent meets the requirements for USP Sterile Water for Injection after a water flush of 1 L per autoclaved sample.

Bacterial Retention

Samples were quantitatively retentive of a minimum *Brevibacterium diminuta* challenge concentration of 1×10^7 CFU/cm² using ASTM F838 methodology.

Thermal and Hydraulic Stress

Samples were steamed at 135° C for 30 minutes and maintained integrity after a forward stress to 100 psid (6895 mbar) and a reverse stress to 30 psid (2069 mbar).

TOC/Conductivity

Samples exhibited less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm per USP <645> after autoclaving and a WHI water flush of 5.5 L at 25° C.

Quality Performance Criteria

This product was designed and manufactured to meet the following specifications:

Toxicity

This product meets the requirements of the USP <88> Safety Test utilizing 0.9% Sodium Chloride extraction.

This product is non-cytotoxic per USP Cytotoxicity MEM Elution Test.

Multiple Sterilization Cycles

Sample integrity was maintained after 3 autoclave cycles of 60 minutes at 126° C.

Maximum Differential Pressure

80 psid (5516 mbar) continuous
100 psid (6895 mbar) intermittent

Peter Eichert
Quality Manager

